Voluson 730 Ultrasound System

NOV 2 2 2000

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1) Submitter's name, address, telephone number, contact person:

Regulatory Management Services

16303 Panoramic Way

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Gary J. Allsebrook

Regulatory Affairs Consultant

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Prepared:

October 11, 2000

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/Usual Name:

Diagnostic Ultrasound System and Accessories

Proprietary Name:

Voluson 730 Diagnostic Ultrasound System and Transducers.

Classification Names:	FR Number	Product Code
Ultrasound Pulsed Echo Imaging System	892.1560	90-IYO
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Diagnostic Ultrasound Transducer	892.1570	90-ITX

3) Identification of the predicate or legally marketed device:

Medison America, Inc believes that Voluson 730 Ultrasound System is substantially equivalent to the currently marketed Voluson 530 System, K940942 and ATL HDI 5000 System (Level 10HDI), K961459.

4) Device Description:

The Voluson 730 Ultrasound System is a general purpose, mobile, software controlled diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data as B-mode, M-mode, Color Flow Doppler (CFM), Continuous Wave (CW) Doppler, Pulsed Wave (PW) Doppler, Power (Amplitude) Doppler (PD) and 3D Volume imaging mode, or as a combination of these modes. The Voluson 730 also gives the operator the ability to measure anatomical structures and

offers analysis packages that provide information that is used to make a diagnosis by competent health care professionals. The Voluson 730 has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

23 different models of transducers are available and any three may be connected at the same time (plus one pencil probe). In addition to the initial operational settings for each transducer preprogrammed in the system, user-customized parameter settings for each transducer may be inserted by the operator and stored for recall as needed via the system control panel. Customization includes transmit focusing, filtering, image enhancement processing, dynamic window curve selection. Controls are also provided to select display format (single and various combinations), to activate zoom features, and to utilize the cine loop function. Patient contact materials have been used in FDA cleared probes or have passed biocompatibility tests (NamSA).

The Voluson 730 uses digital beamforming technology and supports a variety of Linear, Curved and Phased Array probes (plus pencil probe) for wide variety of applications. It is an ultrasound scanner, which provides high resolution, high penetration performance, and various measurement functions. Probes are supported in frequencies from 2.0 MHz to 16.0 MHz. These probes can be applied to a variety of clinical applications such as abdominal, obstetrical, cerebrovascular, peripheral vascular, gynecological and fertility, small parts, neonatal, intraoperative, vascular, abdominal surgery, laparoscopic, muskoloskeletal, transcranial Doppler, pediatric general imaging, prostate, adult cardiology and pediatric cardiology and transesophagael use. The Voluson 730 provides high quality images and various measuring functions. The same clinical uses were cleared for the predicate devices: Kretztechnik Combison/Voluson 530D Ultrasound System K940942 and ATL HDI 5000 Ultrasound System (Level 10 HDI) K961459.

The system can be used to measure distances and calculate areas, circumferences and volumes, as well as calculate the date of delivery by using BPD (biparietal diameter), OFD (occipito-frontal diameter), HC (head circumference), AC (abdominal circumference), AD (abdominal diameter), FL (femur length), CRL (crown rump length), APTD (anteroposterior trunk diameter), TTD (transverse trunk diameter), GS (gestational sac), and LMP (last menstural period.) etc., Cardiac Analysis (volume by area/length, Simpson biplane and singleplane, M-mode analysis, Doppler peak and mean gradients, pressure half time, E/A ratio and continuity equation) and vascular Analysis (resistance index,pulsitility index, % stenosis, ICA/CCA ratio, VF). Biopsy guidelines are provided on screen to assist in the collection of tissue samples, using biopsy guide adapters offered as an optional accessory. Operating Modes of Voluson 730 are B, B/B, B/Quad, M, B/M, PW,B/PW,CW,B/CW, CFM, PD, B/PW/CFM, B/PW/PD, B/CW/CFM,B/CW/PD and 3D Imaging mode. The modes of M use the Sweep method which has its images flow from the left to the right. Voluson 730 supports the Cine function (capable of

Voluson 730 Ultrasound System

storing up to 256 sequential images) and real-time zoom function to the region-of-interest. The system provides the ability to perform remote viewing of images without compression, via Dicom 3.0A compatible output. Management of patient history is possible by image-filing function. High-resolution images are provided by utilizing a technology called digital dynamic receive focusing.

The Voluson 730 Ultrasound System meets the following electromechanical safety standards:

- EN 60601-1 (IEC 601-1,) European Norm, Medical Electrical Equipment
- UL 2601-1, Underwriters Laboratories Standards, Medical Electrical Equipment
- C22.2 No. 601.1, Canadian Standards Association, Medical Electrical Equipment
- CEI/IEC 1157:1992, International Electrotechnical Commission, Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment
- EN 60601-1-2 (IEC 601-1-2,) European Norm, Collateral Standard: Electromagnetic compatibility
- Compliant with the European Medical Device Directive Certificate issued by TUV.

5) Intended Use:

The Voluson 730 System intended uses as defined FDA guidance documents are:

- Abdominal
- Obstetrical
- Neonatal cephalic
- Adult cephalic
- Peripheral vascular
- Gynecological and fertility
- Small parts (breast, thyroid, parathyroid, penis, testes etc.)
- Intraoperative vascular
- Intraoperative neurological
- Abdominal surgery
- Muscular skeletal conventional
- Muscular skeletal superficial (skin)
- Transcranial doppler
- Pediatric general imaging
- Laparoscopic
- Prostate
- Trans-Rectal
- Trans-Vaginal
- Adult cardiology
- Pediatric cardiology

Voluson 730 Ultrasound System

- Transesophagael
- Neonatal

Typical examinations performed using the system are:

- General abdominal and pelvic studies including organ surveys, assessment, and retroperitoneal cavity studies.
- Study of small parts including breasts, shoulders, thyroid, and the abdominal wall.
- Pediatric scans of organs and bony structures.
- Peripheral vascular applications including carotid arteries, legs, arms, feet, and penile artery.
- Monitoring procedures for infertility studies (other than in vitro fertilization).
- First, second and third trimester pregnancy studies.
- Prostate, prostate biopsy guidance, and rectal wall studies.
- Neonatal head studies.
- Transcranial studies of middle cerebral arteries, internal carotid artery, and vertebral arteries.
- Cardiac studies in adults and children.
- Biopsy guidance for tissue or fluid sampling.
- Conventional podiatry scans.
- Intraoperative application including soft tissue structures.

6) Technological Characteristics:

This device operates identical to the predicate devices in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as a 2D and M-mode, Continuous wave Doppler, Spectral Doppler, Color Doppler, Power Doppler, 3D images. Scanhead patient contact materials are biocompatible.

The device's acoustic output limits are:

All Applications:

(Maximum Range)

ISPTA

720 mW/cm2

MI

1.9

The limits are the same as predicate Track 3 devices.



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

NOV 2 2 2000

Medison America, Inc. c/o Mr. Mark Job TÜV Product Service 1775 Old Highway 8 NW, Suite 104 New Brighton, Minnesota 55112-1891

Re: K003525

Voluson 730 Diagnostic Ultrasound System

Regulatory Class: II

21 CFR §892.1550/Procode: 90 IYN 21 CFR §892.1560/Procode: 90 IYO 21 CFR §892.1570/Procode: 90 ITX

Dated: November 13, 2000 Received: November 15, 2000

Dear Mr. Job:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Voluson 730 Ultrasound System, as described in your premarket notification:

Transducer Model Number

SP 4-10 4-10 MHz / 50mm / Linear Array SP 6-12 6.0-12.0 MHz / 40mm / Linear Array SP 10-16 10-16 MHz / 30mm / Linear Array IOL 5-9 5.0-9.0 MHz / 38mm / Linear Array AB 2-5 2.0-5.0 MHz / 40R / 85D / Curved Array

AB 4-8 4.0-8.0 MHz / 40R / 70D / Curved Array IOC 4-8 4.0-8.0 MHz / 40R / 60D / Curved Array LAP 5-8 5.0-8.0 MHz / 40R / 40D / Curved Array IC 5-9 5.0-9.0 MHz / 10R / 150D / Curved Array PA 2-5 2.0-5.0 MHz / 90D / Phased Array PA 4-7 4.0-7.0 MHz / 90D / Phased Array PA 6-8 6.0-8.0 MHz / 90D / Phased Array VSP 6-12 6.0-12 MHz / 40mm / 3D Linear Array RSP 6-12 6.0-12 MHz / 40mm / 3D Linear Array RAB 2-5 2.0-5.0 MHz / 40R / 85D / 3D Curved Array RAB 4-8 4.0-8.0 MHz / 40R / 70D / 3D Curved Array RIC 5-9 5.0-9.0 MHz / 10R / 150D / 3D Curved Array RRE 6-10 6.0-10.0 MHz / 10R / 180D / 3D Curved Array VPA 2-5 2.0-5.0 MHz / 90D / 3D Phased Array VPA 4-7 4.0-7.0 MHz / 90D / 3D Phased Array VTE 4-7 4.0-7.0 MHz / 90D / 3D Phased Array SCW 2.0 2.0 MHz / Pencil Probe PCW 4.0 4.0 MHz / Pencil Probe

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR §807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Paul M. Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

Daniel G. Schultz, M.D.

Captain, USPHS

Acting Director, Division of Reproductive Abdominal, and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosures

4.3 Indications for Use

Ultrasound Device Indications For Use Statement

510(k) Number:

Device Name:

Voluson 730 Ultrasound System

Indications for Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation (*includes simultaneous B-mode)									
Clinical Application	Α	В	М*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal (See Note 7)		N	N	N		N	N		Note 1	Notes 2,3,5
Abdominal		N	N	N		N	N		Note 1	Notes 2,3,5
Intra-Operative (See Note 6)		N	N	N		N	N		Note 1	Notes 2,3,5
Intraoperative Neurological		N	N	N		N	N		Note 1	Notes 2,3,5
Pediatric		N	N	N		N	N		Note 1	Notes 2,3,5
Small Organ (See Note 4)		N	N	N		N	N		Note 1	Notes 2,3,5
Neonatal Cephalic		N	N	N		N	N		Note 1	Notes 2,3,5
Adult Cephalic		N	N	N		N	N		Note I	and the state of the state of
Cardiac		N	N	N	N·	N	N		Note 1	Notes 2,5,8
Transesophageal		N	N	N	N	N	N		Note 1	*Notes 2,5,8
Transrectal		N	N	N		N	N		Note 1	Notes 2,3,5
Transvaginal		N	N	N		N	N		Note 1	Notes 2,3,5
Transurethral										
Intravascular									(C.) - (Vertical)	
Peripheral Vascular		N	N	٠N		N	N		Note 1	Notes 2,3,5
Laparascopic		N	N	N		N	N		Note 1	Note 3,5
Muscular-Skeletal Conventional		N	N	N		N	N		Note 1	Notes 2,3,5
Muscular-Skeletal Superficial		N	N	N		N	N		Note 1	Notes 2,3,5
Others (Specify)										Mc News

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:

Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler

Note 2: 3D Imaging Mode

Note 3: Includes imaging for guidance of biopsy

Note 4: For example: thyroid, testicles, salivary gland, breast, lymph nodes, pediatric and neonatal patients etc.

Note 5: Harmonic Imaging

Note 6: Abdominal organs and peripheral vessel

510(k) Number

Note 7: Includes infertility monitoring of follicle development

Note 8: Color M-mode

Concurrence of CDRH, Office of Device	Evaluation (ODE)
Prescription Use (Per 21 CFR 801.10	9)
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	Prescription Use
(Division Sign-Off)	
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Indications For Use and Radiological Devices	Section 4.3, Page 1
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510(k) Number:

Device Name:

Voluson 730 Ultrasound System

Transducer:

SP 4-10 4.0-10 MHz/50mm/Linear Array

Indications for Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation (*includes simultaneous B-mode)									
Clinical Application	Α	В	М*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic				1						
Fetal										
Abdominal							W W			
Intra-Operative (Specify)										egrandig de ceas
Intraoperative Neurological										egit takki is tektiya bilgiya
Pediatric		N	N	N		N	N		Note 1	Note 5
Small Organ (See Note 4)		N	N	N		N	N		Note 1	Note 5
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
iransesophageal									1, 200	AND AND ASSESSMENT OF THE AND
Transrectal										
Transvaginal									erinare el logia	A STATE OF THE STA
Transurethral									ing the control of th	
Intravascular										
Peripheral Vascular		N	N	N		N	N		Note I	Note 5
Laparascopic										
Muscular-Skeletal Conventional		N.	N	N		· N	N		Note I	Note 5
Muscular-Skeletal Superficial									-21 18	With the war with the train
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:

Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler

Note 4: For example: thyroid, testicles, salivary gland, breast, lymph nodes, pediatric and neonatal patients etc.

Note 5: Harmonic Imaging

Concurrence of CDRH,		

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number_ Indications For Use

003525

Section 4.3, Page 2

Prescription Use (Per 21 CFR 801.109)

510(k) Number:

Device Name:

Voluson 730 Ultrasound System

Transducer:

SP 6-12 6.0-12 MHz/40mm/Linear Array

Indications for Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation (*includes simultaneous B-mode)									
Clinical Application	Α	В	М*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic							** **			
Fetal										
Abdominal										
Intra-Operative (Specify)										- _W /9/5, ¹⁵⁷
Intraoperative Neurological						4.				in the second second
Pediatric		N	N	N		N	N		Note 1	Notes 3,5
Small Organ (See Note 4) Neonatal Cephalic		N	N	N		N	N		Note 1	Notes 3,5
Adult Cephalic	ļ									
Cardiac										
			<u> </u>				****		<u> </u>	
Transesophageal				<u> </u>						
Transrectal									- Sec. (1970)	
Transvaginal										
Transurethral									.25 1.3	a in partition than
Intravascular										
Peripheral Vascular		N	N	N		N	N		Note 1	Notes 3,5
Laparascopic										
Muscular-Skeletal Conventional		N	N	N		· N	N		Note 1	Notes 3,5
Muscular-Skeletal Superficial		N	N	N		N	N		Note 1	Notes 3,5
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other	Indica	ations	or	Mod	es

Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler

Note 3: Includes imaging for guidance of biopsy

Note 4: For example: thyroid, testicles, salivary gland, breast, lymph nodes, pediatric and neonatal patients etc.

Note 5: Harmonic Imaging

Indications For Use

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(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

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scription Use : # CFR 801.109)

510(k) Number:

Device Name:

Voluson 730 Ultrasound System

Transducer:

SP 10-16 10-16 MHz/30mm/Linear Array

Indications for Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Oper					f Operation	n (*includes simultaneous B-mode)			
Clinical Application	Α	В	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative (Specify)										and the second
Intraoperative Neurological									N. CO	And the second of
Pediatric										
Small Organ (See Note 4)		N	N	N		N	N		Note 1	Note 5
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										La La Catalaga de Aleita.
Transrectal										
Transvaginal				-					worker effektion	e viji i i i i i i i i i i i i i i i i i
Transurethral									and the first of the second state of the	e e e e e e e e e e e e e e e e e e e
Intravascular										
Peripheral Vascular									And the Contractor	in a figure
Laparascopic										
Muscular-Skeletal Conventional									cusso sets to	Server of the Server Server
Muscular-Skeletal Superficial		N	N	N		N	N		Note 1	Note 5
Others (Specify)										

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Þ	= new indication;	P = previously cla	eared by FDA:	E= added under	Annendix	F

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Conner	Indica	PIONS.	or h	Mades.

Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler

Note 4: For example: thyroid, testicles, salivary gland, breast, lymph nodes, pediatric and neonatal patients etc.

Note 5: Harmonic Imaging

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Prescription Use (Per 21 CFR 801.109)	()	
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Division of Reproductive Abdominal ENT		

Indications For Use

and Radiological Devices
510(k) Number 5003525

510(k) Number:

Device Name:

Voluson 730 Ultrasound System

Transducer:

IOL 5-9 5.0-9.0 MHz/38mm/Linear Array

Indications for Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as

follows:

		Mode of Operation (*includes simultaneous B-mode)								
Clinical Application	A	В	М*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative (See Note 6)		N	N	N		N	N		Note 1	Note 5
Intraoperative Neurological		N	N	N		N	N		Note 1	Note 5
Pediatric									100 110	ajjaka
Small Organ (Specify)				المجاورة والموارد						
Neonatal Cephalic							-			\$ 100 x 1 2 2 2
Adult Cephalic										
Cardiac										
Transesophageal										·
Transrectal									:	
Transvaginal							· · · · · · · · · · · · · · · · · · ·			
Transurethral										
Intravascular									a stance town	والمراجع والم والمراجع والمراجع والمراجع والمراجع والمراجع والمراجع والمراج
Peripheral Vascular										
Laparascopic									a the grade of the section of the	وهورة ووالمتات والمتعلقة فروادات
Muscular-Skeletal Conventional				**************************************	r					
Muscular-Skeletal Superficial									er en	and a first of the state of the
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:

Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler

Note 5: Harmonic Imaging

Indications For Use

Note 6: Abdominal organs and peripheral vessel

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number

(Per 21 CFR 801.109)

Prescription Use.

510(k) Number:

Device Name:

Voluson 730 Ultrasound System

Transducer: A

AB 2-5 2.0-5.0 MHz/ 40R/85D/Curved Array

Indications for Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

		Mode of Operation (*includes simultaneous B-mode)									
Clinical Application	A	В	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)	
Ophthalmic							-				
Fetal (See Note 7)	1	N	N	N		N	N		Note 1	Notes 3,5	
Abdominal		N	N	N		N	N		Note 1	Notes 3,5	
Intra-Operative (Specify)										en en	
Intraoperative Neurological										(1851)A6(1880)B	
Pediatric											
Small Organ (Specify)									sir .	Strangers	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal									erentako erak erak erak	in in the section of	
Transrectal									Andrew State of the	. The constitution	
Transvaginal							-				
Transurethral									and the second of the second o	oral oral gradultage	
Intravascular											
Peripheral Vascular									. The Karthings, A	sumples savet one	
Laparascopic											
Muscular-Skeletal Conventional									o new orderen	ing adaption of the	
Muscular-Skeletal Superficial									- And American	Springer (1975)	
Others (Specify)											

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other	Indications	or M	lodes:
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Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler

Note 3: Includes imaging for guidance of biopsy

Note 5: Harmonic Imaging

Note 7: Includes infertility monitoring of follicle developement

Concurrence of CDRH, Office of Device Eva	luation (ODE)	
	Prescription Use	
(Division Sign-Off)	(Per 21 CFR 801.109)	
Division of Reproductive, Abdominal, ENT,		

Indications For Use

and Radiological Devices
510(k) Number <u>4003525</u>

510(k) Number:

Device Name:

Voluson 730 Ultrasound System

Transducer:

AB 4-8 4.0-8.0 MHz/40R/70D/Curved Array

Indications for Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	T	Mode of Operation (*includes simultaneous B-mode)								
Clinical Application	A	В	М*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal (See Note 7)		N	N	N		N	N		Note 1	Notes 3,5
Abdominal		N	N	N		N	N		Note 1	Notes 3,5
Intra-Operative (Specify)										track to the state
Intraoperative Neurological									- 28	unu samuang pa
Pediatric		N	N	N		N	N		Note 1	Notes 3,5
Small Organ (Specify)									Å	nada — gardetagas etak
Neonatal Cephalic										
Adult Cephalic										
Cardiac										ete sineta eta eta
Transesophageal										
Transrectal									and the second second	
Transvaginal									11.8000	en e alle tres en excleta
Transurethral						e e			1 / New 2500 58	en vinger i ver en
Intravascular	1									
Peripheral Vascular	1								e services and the	ng sakaran na makada
Laparascopic	\dagger									
Muscular-Skeletal Conventional		N	N	N		N	N		Note 1	Notes 3,5
Muscular-Skeletal Superficial									terton a	error sakaran saka
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:

Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler

Note 3: Includes imaging for guidance of biopsy

Note 5: Harmonic Imaging

Note 7: Includes infertility monitoring of follicle developement

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, Indications For Use and Radiological Devices

Section 4.3, Page 7 510(k) Number _ £ 003525

510(k) Number:

Device Name:

Voluson 730 Ultrasound System

Transducer:

IOC 4-8 4.0-8.0 MHz/40R/60D/Curved Array

Indications for Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation (*includes simultaneous B-mode)									
Clinical Application	Α	В	М*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal				-						·
Abdominal										
Intra-Operative (See Note 6)		N	N	N	-	N	N		Note 1	Note 5
Intraoperative Neurological		N	N	N		N	N		Note 1	Note 5
Pediatric										·
Small Organ (Specify)									ge rayed vi	enting of the state of States
Neonatal Cephalic									nje tekster i sama kaland	The state of the state of the
Adult Cephalic										7 44 7 45 4
Cardiac									and the same of the same of the same	وروار دراد داده العرضور الداد
Transesophageal										
ansrectal				·					comment of the Market	The weak was the second
Transvaginal										
Transurethral									117 May 2011 148	The control of the second
Intravascular										· · · · · · · · · · · · · · · · · · ·
Peripheral Vascular									والإنجادي والمراجع	and the second
Laparascopic										
Muscular-Skeletal Conventional									salas et al. 1915 et eta et	in kood kood wide sa sa sa sa
Muscular-Skeletal Superficial									eqt .	QUALITY NO
Others (Specify)										

V = new indication;			
		lded under	

Other	Indicati	ons or	Modes:

Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler

Note 5: Harmonic Imaging

Note 6: Abdominal organs and peripheral vessel

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Concurrence of CDRH, Office of De	evice Evaluation (ODE)
Prescription use (Per 21 CFH	901.109)
	Prescription Use
	Per 21 CFR 801.109)
(Division Sign-Off)	

Division of Reproductive, Abdominal, ENT,

and Radiological Devices Indications For Use

510(k) Number <u>K</u> 003 5 25

510(k) Number:

Device Name:

Voluson 730 Ultrasound System

Transducer:

LAP 5-8 5.0-8.0 MHz/40R/40D/Curved Array

Indications for Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation (*includes simultaneous B-mode)									
Clinical Application	A	В	М*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal							-			
Abdominal										W 1 - 1 - 1
Intra-Operative (Specify)			ļ				:			i programa
Intraoperative Neurological										er, r — Novers Voltagest
Pediatric										
Small Organ (Specify)									40. sa	un Ada — de Lucio establica
Neonatal Cephalic									The state of the s	and the second section
Adult Cephalic										
Cardiac										real englishmen
Transesophageal										
Transrectal									and the second	and the agree to the least of the least
Transvaginal				-						
Transurethral									Market salah	and the second of the second
Intravascular										
Peripheral Vascular				·					. Vide	the product of the second seco
Laparascopic		N	N	N		N	N		Note 1	Notes 5
Muscular-Skeletal Conventional								-	and representative territories	n dag magan ini dag mengangan
Muscular-Skeletal Superficial									njerie V. n	engen samme state
Others (Specify)										

N	= new indication:	P = previou	siv cleare	d by FDA	F= added under	Annendiy F

Other Indications or Modes:

Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler

Note 5: Harmonic Imaging

Concurrence of CDRH, Office of De	evice Evaluation (ODE)	
Prescription Use (Per 21 CFF		
	Prescription Use	-
	(Per 21 CFR 801.109	31
(Division Sign_Off)	21 Carr 001.105	•

Division Sign-Off)
Division of Reproductive, Abdominal, ENT,

Indications For Usand Radiological Devices
510(k) Number 603525

510(k) Number:

Devace Name:

Voluson 730 Ultrasound System

Transducer:

IC 5-9 5.0-9.0 MHz/10R/150D/Curved Array

Indications for Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode o	f Operation	(*includes simu	Itaneous B-r	node)	
Clinical Application	Α	В	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal (See Note 7)		N	N	N		N	N		Note 1	Notes 3,5
Abdominal										
Intra-Operative (Specify)										en and
Intraoperative Neurological										e erangely, et qui par
Pediatric										
Small Organ (Specify)						-			15 (8.1.4.)	Section 1
Neonatal Cephalic									15 (15),	
Adult Cephalic										er de de la company
Cardiac									na karananggana	ath you was
Transesophageal										
Transrectal		N	N	N		N	N		Note 1	Notes 2.3
Transvaginal		N	N	N		N	N		Note 1	Notes 2,3
Transurethral									assert same	and the second second
Intravascular										
Peripheral Vascular									and the second second	
Laparascopic										
Muscular-Skeletal Conventional									es est of to est to include	us hat a Pharis, is to a
Muscular-Skeletal Superficial									A China	1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -
Others (Specify)										· · · · · · · · · · · · · · · · · · ·

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- 1	√ = new indication;	P = previousis	Cleared by FIIA	E= added	under /	Annendiv I	۲.

Other	Indicat	ione or	Modes:

Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler

Note 3: Includes imaging for guidance of biopsy

Note 5: Harmonic Imaging

Note 7: Includes infertility monitoring of follicle developement

510(k) Number_

Concurrence of CDRH, Office of Device	e Evaluation (ODE)
Prescription Use (Per 21 CFR 801.1	09)
	Prescription Use
	(Per 21 CFR 801.109)
(Division Sign-Off)	
Division of Reproductive Abdominal ENT	·

Indications For Use

and Radiological Devices

510(k) Number:

Device Name:

Voluson 730 Ultrasound System

Transducer:

PA 2-5 2.0-5.0 MHz/ 90D/Phased Array

Indications for Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	1	Mode of Operation (*includes simultaneous B-mode)									
Clinical Application	Α	В	М*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)	
Ophthalmic	1										
Fetal											
Abdominal		N	N	N	N	N	N		Note 1	Notes 5,8	
Intra-Operative (Specify)										Turke or the engage	
Intraoperative Neurological										i na gweige i Margadowa. Ta	
Pediatric											
Small Organ (Specify)									offwok figure, parent	Market to the second	
Neonatal Cephalic									nan e e e e e e e e e e e e e e e e e e	and the state of t	
Adult Cephalic		N	N	N	N	N	N		Note 1	Notes 5,8	
Cardiac		N	N	N	N	N	N		Note 1	Notes 5,8	
Transesophageal											
Transrectal									s company and the	est our teams of the state of	
Transvaginal									···		
Transurethral			-						, Le Service et al	ing the section is	
Intravascular									•		
Peripheral Vascular									er general part of the part of the	A Superior of the second design	
Laparascopic											
Muscular-Skeletal Conventional									uar - r sturgstate	Anti- James James	
Muscular-Skeletal Superficial									mis summaris (a)	ୀୟ ନିନ୍ଦ୍ରକୁ ପୁର୍ବିଷ୍ଟ ବିହାର ପ୍ରତ୍ୟକ୍ତ ଅ ଧି	
Others (Specify)											

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:

Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler

Note 5: Harmonic Imaging Note 8: Color M-Mode

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Concurrence of 0	CDRH.	Office/	of Device	Evaluation	(ODE)
Concurrence of C	Prescriptio	n Use (Per	21 CFR 801.10	9)	(ODL)

Prescription Use ______(Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

Indications For Use and Radiological Devices

510(k) Number <u>KOD3525</u>

510(k) Number:

Device Name:

Voluson 730 Ultrasound System

Transducer:

PA 4-7 4.0-7.0 MHz/ 90D/Phased Array

Indications for Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation (*includes simultaneous B-mode)											
Clinical Application	Α	В	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)		
Ophthalmic							-			7		
Fetal												
Abdominal										 		
Intra-Operative (Specify)										80		
Intraoperative Neurological									-	getting of e		
Pediatric		N	N	N	N	N	N		Note 1	Notes 5,8		
Small Organ (Specify) Neonatal Cephalic					_				right year of the control	en e		
•									gateria de la sesa	4d		
Adult Cephalic												
Cardiac		N	N	N	N	N	N		Note 1	Notes 5,8		
Transesophageal												
Transrectal									one of the second	en de la descripción de la companya		
Transvaginal												
Transurethral									a tenur dia	nan arate pasa		
Intravascular												
Peripheral Vascular									an egittika ing i sanga san	and great a respe		
Laparascopic												
Muscular-Skeletal Conventional									Sever	erre derigner dans		
Muscular-Skeletal Superficial						_				green way a street		
Others (Specify)												

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т.	I = new indication;	- 1	- previousiy	v cieare.	กท	' H }A *	· -	anned	under	Appendix	

Other	Indica	tions o	r Mode	٠.
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Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler

Note 5: Harmonic Imaging Note 8: Color M-Mode

Concurrence of CDRH, Office of Device	Evaluation (ODE)
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	Prescription Use
Sign_Off)	(Per 21 CFR 801 109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

Indications For Use and Radiological Devices

510(k) Number <u>K003525</u>

510(k) Number:

Device Name:

· Voluson 730 Ultrasound System

Transducer:

PA 6-8 6.0-8.0 MHz/ 90D/Phased Array

Indications for Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation (*includes simultaneous B-mode)											
Clinical Application	A	В	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)		
Ophthalmic								·				
Fetal												
Abdominal	1						-					
Intra-Operative (Specify)						·				or history		
Intraoperative Neurological									- A-	gen i gantar keliji jar		
Pediatric												
Small Organ (Specify)									Lington Consultation	er fregjage et kjelet et et t		
Neonatal Cephalic		N	N	N	N	N	N		Note 1	Notes 5,8		
Adult Cephalic						:						
Cardiac		N	N	N	N	N	N		Note 1	Notes 5,8		
Transesophageal												
Transrectal									ray or a superior of the second			
Transvaginal												
Transurethral									garage and the same	egi a tan iyana ganana iya yan garas		
Intravascular												
Peripheral Vascular	1								salah permetangan bahar	and the second section of		
Laparascopic			-							· · · · · · · · · · · · · · · · · · ·		
Muscular-Skeletal Conventional					,	•			er Marce — La e y e Ministra	eng mgalaggamaga, tu		
Muscular-Skeletal Superficial						- 12 1			-	a stronger		
Others (Specify)												

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other	Indications	ÒΓ	Modes:
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Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler

Note 5: Harmonic Imaging Note 8: Color M-Mode

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

Indications For Usand Radiological Devices

510(k) Number <u>+ 63525</u>

Prescription Use _______ (Per 21 CFR 801.109)

510(k) Number:

Device Name:

Voluson 730 Ultrasound System

Transducer:

VSP 6-12 6.0-12 MHz/40mm/3D Linear Array

Indications for Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation (*includes simultaneous B-mode)									
Clinical Application	Α	В	М*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal										
Abdominal									- !	
Intra-Operative (See Note 6)		N	N	N		N	N		Note 1	Notes 2,3,5
Intraoperative Neurological									e in grand	en. II. stelle græk
Pediatric		N	N	N		N	N		Note 1	Notes 2,3,5
Small Organ (See Note 4)		N	N	N		N	N	·	Note 1	Notes 2,3,5
Neonatal Cephalic									20 A TO	and the state of the state of
Adult Cephalic										
Cardiac									HARAGE E RESERVED	The second s
Transesophageal										
Transrectal									the state of the section of the sect	1 National Control of the Control of
Transvaginal		•								
Transurethral						· · · · · · · · · · · · · · · · · · ·			e tje kilometer	ng ng mining panggang gangg
Intravascular										
Peripheral Vascular		N	N	N		N	N		Note 1	Notes 2,3,5
Laparascopic										
Muscular-Skeletal Conventional									September 1997 And Andrews	er - Karaman Proges
Muscular-Skeletal Superficial		N	N	N		N	N		Note 1	Notes 2,3,5
Others (Specify)										

<pre>I = new indication;</pre>				= addec			

Other	India	ations	0- N	Andes:
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Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler

Note 2: 3D Imaging Mode

Note 3: Includes imaging for guidance of biopsy

Note 4: For example: thyroid, testicles, salivary gland, breast, lymph nodes, pediatric and neonatal patients etc.

Note 5: Harmonic Imaging Note 6: Abdominal organs

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

Indications For Use

510(k) Number:

Device Name:

Voluson 730 Ultrasound System

Transducer:

RSP 6-12 6.0-12 MHz/40mm/3D Linear Array

Indications for Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

		Mode of Operation (*includes simultaneous B-mode)								
Clinical Application								Other (Specify)		
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative (See Note 6)		N	N	N		N	N		Note 1	Notes 2,3,5
Intraoperative Neurological										. No. 11 of the State of North State of North State of St
Pediatric		N	N	N		N	N		Note 1	Notes 2,3,5
Small Organ (See Note 4)		N	N	N		N	N	·	Note.1	Notes 2,3,5
Neonatal Cephalic									e de la companya	ing the majors distribute
Adult Cephalic										
Cardiac									1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	and the second second
Transesophageal									**	
Transrectal									. Company	to the second second second
Transvaginal										
Transurethral									en videan	James Toward Spilling the
Intravascular										···
Peripheral Vascular		N	N	N		N	N		Notesta	Notes 2,3,5
Laparascopic										
Muscular-Skeletal Conventional										Children Strates (Allert Heisen Terke
Muscular-Skeletal Superficial		N	N	N		N	N		Note I	Notes 2,3,5
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other	Indica	tions	or l	Modes:

Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler

Note 2: 3D Imaging Mode

Note 3: Includes imaging for guidance of biopsy

Note 4: For example: thyroid, testicles, salivary gland, breast, lymph nodes, pediatric and neonatal patients etc.

Note 5: Harmonic Imaging Note 6: Abdominal organs

Concurrence of	CDRH Office	of Device Evalu	ation (ODE)
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(Division Sign-Off)

Division of Reproductive, Abdominal, ENT.

Indications For Useand Radiological Devices

510(k) Number <u>K</u> 00 3525

Prescription Use _____(Per 21 CFR 801.109)

510(k) Number:

Device Name:

Voluson 730 Ultrasound System

Transducer:

RAB 2-5 2.0-5.0 MHz/40R/85D/3D Curved Array

Indications for Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation (*includes simultaneous B-mode)									
Clinical Application	Α	В	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal (See Note 7)		N	N	N		N	N		Note 1	Notes 2,3,5
Abdominal		N	N	N		N	N		Note 1	Notes 2,3,5
Intra-Operative (See Note 6)										
Intraoperative Neurological									.5-	ne Awaran na ng
Pediatric									· · · · · · · · · · · · · · · · · · ·	
Small Organ (Specify)									nguna ^T ilan kepad	second transfer
Neonatal Cephalic									Togeth, Little	entra de la compansión de
Adult Cephalic										
Cardiac								-	elektrik berberalan	a. Janger og
Transesophageal										
Transrectal										the first way to part whe
Transvaginal										
Transurethral									Section 18	1.00 to 6.00 to 1.00 to
Intravascular										
Peripheral Vascular									الرواد المنامر فيتنوف والماد	the straightful the contract
Laparascopic										
Muscular-Skeletal Conventional		N	N	N		N	N		Note 1	Notes 2,3,5
Muscular-Skeletal Superficial						-			Anderson (all 1)	
Others (Specify)										

<pre>! = new indication;</pre>			
		E= added under	

Other	Indications	۸r	Modec
Oute	HRGICALIONS.	4 12	IVIOURS.

Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler

Note 2: 3D Imaging Mode

Note 3: Includes imaging for guidance of biopsy

Note 5: Harmonic Imaging

Note 7: Includes infertility monitoring of follicle developement

Concurrence of CDRH Office of Device I	Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109))
	Prescription Use
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(Division of the company)	(Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

Section 4.3, Page 16

Indications For Usand Radiological Devices

510(k) Number <u>400352</u>

510(k) Number:

Device Name:

Voluson 730 Ultrasound System

Transducer:

RAB 4-8 4.0-8.0 MHz/40R/70D/3D Curved Array

Indications for Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation (*includes simultaneou								eous B-mode)		
Clinical Application	Α	В	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)	
Ophthalmic											
Fetal (See Note 7)		N	N	N		N	N		Note 1	Notes 2,3,5	
Abdominal		N	N	N		N	N		Note 1	Notes 2,3,5	
Intra-Operative (See Note 6)		N	N	N		N	N		Note 1	Notes 2,3,5	
Intraoperative Neurological											
Pediatric					-						
Small Organ (Specify)									ese ta	production of the second	
Neonatal Cephalic	↓									10 10 10 10 10 10 10 10 10 10 10 10 10 1	
Adult Cephalic	<u> </u>										
Cardiac	1								ige in elektrosia	and the same	
Transesophageal											
Transrectal										mark et aparte filo	
Transvaginal	1										
Transurethral							*		. Propagaretes 3.3	a Systems	
Intravascular											
Peripheral Vascular	1	 	1						500 000	and the second	
Laparascopic	1		1								
Muscular-Skeletal Conventional		N	N	N		N	N		Note 1	Notes 2,3,5	
Muscular-Skeletal Superficial									yers seal	- 	
Others (Specify)											

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other In-	dications	or Mod	es:
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Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler

Note 2: 3D Imaging Mode

Note 3: Includes imaging for guidance of biopsy

Note 5: Harmonic Imaging

Note 6: Abdominal organs

Note 7: Includes infertility monitoring of follicledevelopement

	te of Device Evaluation (ODE)
Pinscipnon use (r	rai 21 OFN 601.109)
	Prescription Use
<u> </u>	— (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

Indications Forates Radiological Devices

510(k) Number <u>4003525</u>

510(k) Number:

Device Name:

Voluson 730 Ultrasound System

Transducer.

RIC 5-9 5.0-9.0 MHz/10R/150D/3D Curved Array

Indications for Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation (*includes simultaneous B-mode)											
Clinical Application	Α	В	М*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)		
Ophthalmic												
Fetal (See Note 7)		N	N	N		N	N		Note 1	Notes 2,3,5		
Abdominal												
Intra-Operative (Specify)												
Intraoperative Neurological										wer (* 1. etc.)		
Pediatric												
Small Organ (Specify)									, essent	as contraction		
Neonatal Cephalic		N	N	N		N	N		Note 1	Notes 2,3,5		
Adult Cephalic												
Cardiac										e e e e e		
Fransesophageal												
Transrectal		N	N	N		N	N		Note 1	Notes 2,3,		
Fransvaginal		N	N	N		N	N		Note 1	Notes 2,3,5		
[ransurethral									er er er er er er er er	and the second second		
ntravascular												
Peripheral Vascular										and the same of th		
aparascopic		\dashv										
Muscular-Skeletal Conventional									Section 1981	Million de la compania		
Muscular-Skeletal Superficial									***	+ w *		
Others (Specify)												

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other	Indic	ations	ori	Modes:

Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler

Note 2: 3D Imaging Mode

Note 3: Includes imaging for guidance of biopsy

Note 5: Harmonic Imaging

Note 7: Includes infertility monitoring of follicledevelopement

Concurrence of CDRH, Office o	Device Evaluation (ODE)
Prescription Use (Per 2)	
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	Prescription Use
	(Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

Indications For Usend Radiological Devices

510(k) Number <u>K003525</u>

510(k) Number:

Device Name:

Voluson 730 Ultrasound System

Transducer:

RRE 6-10 6.0-10.0 MHz/10R/180D/3D Curved Array

Indications for Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation (*includes simultaneous B-mode)										
Clinical Application	Α	В	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)	
Ophthalmic											
Fetal (Specify)						-,					
Abdominal											
Intra-Operative (Specify)						-				turn i wak	
Intraoperative Neurological										. May provide the Modes	
Pediatric											
Small Organ (Specify)									नोकार . र∰	१९४५ - विद्यालयोग १००५ सम्ब	
Neonatal Cephalic									1. Bigwer 10.8	<u>and the second </u>	
Adult Cephalic											
Cardiac									ne. hisaga	and the same of th	
Transesophageal											
Transrectal		N	N	N		N	N		Note 1	Notes 2,3,5	
Transvaginal											
Transurethral									. 150 WY 744	وي المعادي الم	
Intravascular		<u> </u>									
Peripheral Vascular									1.000	and the second of the two	
Laparascopic								-			
Muscular-Skeletal Conventional									en o la service d'ente	Land Comment West (1997)	
Muscular-Skeletal Superficial									· · · · · · · · · · · · · · · · · · ·	a jakayaya .	
Others (Specify)							-				

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other	Indica	tione	or N	Andac:

Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler

Note 2: 3D Imaging Mode

Note 3: Includes imaging for guidance of biopsy

Note 5: Harmonic Imaging

Concurrence of CDRH, Office	e of Device Evaluation (ODE)
Prescription Use (I	Per 21 CFR 801.109)

(Division Sign-Off)

510(k) Number

Division of Reproductive, Abdominal, ENT,

Indications For Useand Radiological Devices

Prescription Use. (Per 21 CFR 801.109)

510(k) Number:

Device Name:

Voluson 730 Ultrasound System

Transducer:

VPA 2-5 2.0-5.0 MHz/ 90D/3D Phased Array

Indications for Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation (*includes simultaneous B-mode)											
Clinical Application	Α	В	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)		
Ophthalmic												
Fetal	1											
Abdominal		N	N	N	N	N	N		Note 1	Notes 2,5,8		
Intra-Operative (Specify)										· .		
Intraoperative Neurological				·			- 2		w .	er a garet ge		
Pediatric												
Small Organ (Specify)									1931. on 11 8. 19 .	i esa est gran acidago.		
Neonatal Cephalic							-		nanto i nosta k	and a series was no		
Adult Cephalic		N	N	N	N	N	N		Note 1	Notes 2,5,8		
Cardiac		N	N	N	N	N	N		Note 1	Notes 2,5,8		
Transesophageal									*** - *********************************			
Transrectal									est i et este el considerado	and the second second		
Transvaginal												
Transurethral									AUGUS SALAN	n egyete wee		
Intravascular			\dashv									
Peripheral Vascular			\dashv						er errorikasi	and the property of the second		
Laparascopic		_										
Muscular-Skeletal Conventional									No. 19 April 19	set ye		
Muscular-Skeletal Superficial				·					N/			
Others (Specify)												

= new indication:				
			added unde	

Other:	Indi	cations	or	Mode	·s:
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Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler

Note 2: 3D Imaging Mode Note 5: Harmonic Imaging Note 8: Color M-Mode

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use. (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

Indications For Usand Radiological Devices 510(k) Number <u>K003525</u>

510(k) Number:

Device Name:

Voluson 730 Ultrasound System

Transducer:

VPA 4-7 4.0-7.0 MHz/ 90D/3D Phased Array

Indications for Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	T				Mode o	f Operation	(*includes simu	ltaneous B-n	node)	
Clinical Application	Α	В	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal	 						· · · · · · · · · · · · · · · · · · ·			
Abdominal										
Intra-Operative (Specify)								·		s to
Intraoperative Neurological								·	-	. Proposition in
Pediatric		N	N	N	N	N	N		Note 1	Notes 2,5,8
Small Organ (Specify)						·	·			i galassa gagan a gagay
Neonatal Cephalic									tiste out of out	ma, sesele con se
Adult Cephalic										
Cardiac		N	N	N	N	N	N	-:	Note 1	Notes 2,5,8
Transesophageal										
Transrectal									es a les four pares de son	in a second constitution
Transvaginal										
Transurethral									n washin sayarrana	, persional
Intravascular										× •
Peripheral Vascular	 	\vdash							en i en	ter transferences
Laparascopic		<u> </u>				-				
Muscular-Skeletal Conventional									w na til mindelska at at	r der electrica
Muscular-Skeletal Superficial										per mages
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other	Indi	cations	or N	Andes
Oute	HILL	Caliblis	o	mucs:

Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler

Note 2: 3D Imaging Mode Note 5: Harmonic Imaging Note 8: Color M-Mode

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(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

Indications For Use and Radiological Devices

510(k) Number <u>K003525</u>

Prescription Use ___

(Per 21 CFR 801.109)

510(k) Number:

Device Name:

Voluson 730 Ultrasound System

Transducer:

VTE 4-7 4.0-7.0 MHz/ 90D/ 3D Phased Array

Indications for Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation (*includes simultaneous B-mode)											
Clinical Application	Α	В	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)		
Ophthalmic	T				•							
Fetal												
Abdominal												
Intra-Operative (Specify)												
Intraoperative Neurological										in the same of		
Pediatric												
Small Organ (Specify)										en Linguest in Norge		
Neonatal Cephalic									1.789.44	t was a right of		
Adult Cephalic												
Cardiac		N	N	N	N	N	N		Note 1	Notes 2,5,8		
Transesophageal		N	N	N	N	N	N		Note 1	Notes 2,5,8		
Transrectal									Secretary Secretary	a and a supplemental trans		
Transvaginal												
Transurethral									ranga terapangan	120 table 100 to 8		
Intravascular							······································					
Peripheral Vascular									e e e e e e e e e e e e e e e e e e e	nesta en en		
Laparascopic	1-1											
Muscular-Skeletal Conventional									- 10 or 200	Mose My Jenning		
Muscular-Skeletal Superficial						·				www.com		
Others (Specify)												

1	<pre> = new indication;</pre>	P = previously	v cleared by FDA:	E= added under	Appendix	F.

Other Indications or Modes	Other	Indicat	ions or	Modes
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Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler

Note 2: 3D Imaging Mode Note 5: Harmonic Imaging Note 8: Color M-Mode

Concurrence	of CDRH. Offi	ce of Device Evaluation (ODE
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	Prescription Use	(Per 21 CFR 801 109)	

Prescription Use _____ (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

Indications For Use and Radiological Devices

510(k) Number <u>K003525</u>

510(k) Number:

Device Name: Transducer:

Voluson 730 Ultrasound System

SCW 2.0 2.0 MHz / Pencil Probe

Indications for Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation (*includes simultaneous B-mode)											
Clinical Application	Α	В	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)		
Ophthalmic												
Fetal				· · · · · · · · · · · · · · · · · · ·			-					
Abdominal												
Intra-Operative (Specify)								7.2		4115		
Intraoperative Neurological										Window 1		
Pediatric												
Small Organ (Specify)									post esta	in Albania in es		
Neonatal Cephalic									u erkir i riyak sa a	1000		
Adult Cephalic												
Cardiac					N					2.5		
Transesophageal									····			
Transrectal									1, 0.560.3	are the con-		
Transvaginal		-										
Transurethral									Nether to the same			
Intravascular												
Peripheral Vascular										e January engagen o		
Laparascopic												
Muscular-Skeletal Conventional									. 48.0			
Muscular-Skeletal Superficial												
Others (Specify)										-		

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Concurrence of CDRIA, Office of Device Evaluation (ODE)
Prescription Uses (Per 21 CFR 801.109)

(Division Sign-Off)

Indications For Use

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number <u>K003525</u>

Prescription Use (Per 21 CFR 801.109)

510(k) Number:

Device Name: Transducer:

Voluson 730 Ultrasound System

PCW 4.0 4.0 MHz / Pencil Probe

Indications for Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	T	Mode of Operation (*includes simultaneous B-mode)											
Clinical Application	Α	В	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)			
Ophthalmic													
Fetal													
Abdominal		ļ											
Intra-Operative (Specify)		l											
Intraoperative Neurological										i i i i i i i i i i i i i i i i i i i			
Pediatric					N								
Small Organ (Specify)									, ys. viet	e proposition of the experimental and			
Neonatal Cephalic									101 000				
Adult Cephalic													
Cardiac	1				N								
Transesophageal										138			
Transrectal -	1								ar an ang an	particular in a constant of the			
Transvaginal													
Transurethral	1								1				
Intravascular	1												
Peripheral Vascular	1-				N				e e a e e e e e e e e e e e e e e e e e	er e agent are e e en age			
Laparascopic	1												
Muscular-Skeletal Conventional										The Co			
Muscular-Skeletal Superficial													
Others (Specify)													

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Concurrence of CDRH,	Office of	Device	Evaluation	(ODE)
/ Prescriptio	n Use (Per 21	CFR 801.10	} }	

Prescription Use. (Per 21 CFR 801.109)

(Division Sign-Off)

Indications For Use

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number